

Thesis Project Portfolio

**“Bugs For Drugs”: Encapsulation of a Cooperative Bacterial Consortia as a Therapeutic to
Resolve Recurrent *C. difficile* Infection**

(Technical Report)

**A Sociotechnical and Ethical Analysis of Responsibility for Merck’s Vastly Harmful
Arthritis Drug Vioxx**

(STS Research Paper)

An Undergraduate Thesis

Presented to the Faculty of the School of Engineering and Applied Science
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Bachelor of Science, School of Engineering

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Table of Contents

Therapeutic Safety, Efficacy, and Accessibility

“Bugs For Drugs”: Encapsulation of a Cooperative Bacterial Consortia as a Therapeutic to Resolve Recurrent *C. difficile* Infection

A Sociotechnical and Ethical Analysis of Responsibility for Merck’s Vastly Harmful Arthritis Drug Vioxx

Analysis of Factors Contributing to and Impeding the Success of Biotherapeutic VOWST

Sociotechnical Synthesis

Therapeutic Safety, Efficacy, and Accessibility

My technical design project and STS research project both address issues in therapeutic development and clinical use, specifically considering their downstream effect on patients. The safety, efficacy, and accessibility of therapeutics in healthcare heavily impacts patients, and deficiencies in these crucial elements of therapeutics often have severe consequences. My thesis work collectively considers these elements, the issues that cause such deficiencies, and the impact on patients. However, the individual components of this work differ by focusing on addressing different issues. My technical design work focuses on addressing shortcomings in the efficacy and accessibility of therapeutics through the design and development of a novel biotherapeutic, while my STS research focuses more heavily on safety of therapeutics by an ethical case study and analysis of a controversial and risky drug.

My technical project sought to design a therapeutic for *Clostridioides difficile* (*C. diff*) infections that addresses the insufficiency of current treatments. *C. diff* infection (CDI) is a bacterial infection with high rates of recurrence, and current treatments are either ineffective at resolving infection and preventing recurrence or are invasive, inaccessible, and unappealing. Building off of prior work, my capstone partner and I focused on designing a safe/accessible material and noninvasive method to effectively deliver a therapeutic consortia of bacteria to the intestine. We have successfully developed a method for encapsulating these bacteria within hydrogel microparticles that can be orally ingested. Our work has also identified carboxymethyl cellulose as a suitable material capable of protecting encapsulated bacteria from physiological conditions present in the gastrointestinal tract.

My STS research also focuses on a therapeutic's development, use, and patient impact, but focuses more on safety through an ethical case study of the drug Vioxx, which was developed by Merck & Co. to treat arthritis. After 5 years on the market, Vioxx was recalled in 2004 due to evidence of significant cardiovascular risk. Controversy arose, as Merck was aware of this risk and misrepresented data throughout development and marketing to minimize the perceived risk. In my analysis, I employ the STS framework of Actor-Network theory (ANT) and the ethical concept of passive responsibility to identify a network of actors involved in addition to Merck and determine the level of responsibility each actor possesses for the negative consequences caused by the clinical use of Vioxx.

Both projects significantly impacted my work on the other by expanding my knowledge, experience, and outlook. By working to design a novel biotherapeutic in my technical project, I became more aware of the complexity of the therapeutic development process. Despite working in the early stages of this process, we worked with the future in mind, and therefore, considered many of the same actors as those involved in the case of Vioxx. The experience and knowledge gained from this provided me with the ability to do more effective research into Vioxx and conduct a more insightful analysis. Through my STS research, I learned a lot about the direct and severe negative consequences that scientific misconduct/negligence in therapeutic development can have on patients. As a result, I conducted a more conscious effort to maintain scientific

integrity and always prioritize patient safety in my own therapeutical development work in my technical project. Collectively, these projects have increased my awareness and care for effective innovation and ethical responsibility in healthcare research as a biomedical engineer.